

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

**IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION**

MDL NO. 2740

SECTION “N” (5)

THIS DOCUMENT RELATES TO:

ALL CASES

HON. KURT D. ENGELHARDT

DEFENDANT FACT SHEET – PRODUCT IDENTIFICATION

Within sixty (60) days of receiving a substantially completed Plaintiff Fact Sheet (“PFS”), Defendants Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S., LLC, and Winthrop US (collectively referred to as “Defendants”) must complete and serve this Defendant Fact Sheet (“DFS”) and identify or provide DOCUMENTS and/or data responsive to the questions set forth below for each such Plaintiff. Defendants must supplement their responses to the extent that additional information is provided by Plaintiff in a supplemental PFS, within sixty (60) days of receiving the supplemental information. In the event the DFS does not provide YOU with enough space to complete YOUR responses or answers, please attach additional sheets if necessary. Please identify any DOCUMENTS that YOU are producing as responsive to a question or request by bates number.

DEFINITIONS & INSTRUCTIONS

As used herein, “YOU,” “YOUR,” or “YOURS” means the responding DEFENDANTS.

“DEFENDANTS” shall mean and refer to those companies involved in the development, manufacture and distribution of the drugs known as Taxotere (Docetaxel) including Sanofi S.A., Aventis Pharma S.A., Sanofi-Aventis U.S., LLC, and Winthrop US shall each answer each document request and question that not only calls for YOUR knowledge, but also for all knowledge that is available to YOU by reasonable inquiry, including inquiry of YOUR "officers," "directors," "agents," "employees," and attorneys.

As used herein, the phrase “HEALTHCARE PROVIDER” means: any physician or other individual healthcare provider, health care facility, clinic, hospital or hospital pharmacy identified by full name and address in PFS Section Sections V. 13 and V.14 who administered, prescribed, and/or dispensed Taxotere (Docetaxel) to the Plaintiff.

“WHOLESALE DISTRIBUTION” means distribution of prescription drugs to persons other than a consumer or patient, as defined in U.S. Code of Federal Regulations, 21 CFR 205.3.

“WHOLESALE DISTRIBUTOR” means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions, as defined in U.S. Code of Federal Regulations, 21 CFR 205.3.

“REMUNERATION” means anything of value, directly or indirectly, overtly or covertly, in cash or in kind, including but not limited to monetary payment, compensation, incentives, preceptorship fees, gifts, entertainment, sports and/or concert tickets, speaker fees, grants, SAMPLES, reimbursement assistance, beneficiary inducements, wellness programs, patience assistance programs, transportation and/or lodging assistance, adherence to treatment regimen programs, incentives or inducements to remain in network, navigator/care coordination programs, end of life and/or palliative care programs, third party payments of premiums, or any other inducements or programs.

As used herein, the term “DOCUMENT” SHALL, consistent with Federal Rule of Civil Procedure 34(a)(1)(A), refer to any “designated documents or electronically stored information – including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations – stored in any medium form which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form.”

If YOU are aware that any DOCUMENT that was, or might have been, responsive to any sections of this DFS which concern or relate to Plaintiff or Plaintiff’s Named Facilities was destroyed, erased, surrendered or otherwise removed from YOUR possession, custody or control, at any time, provide, to the maximum extent possible, the following information: (a) the nature of the DOCUMENT (e.g., letter, memorandum, contract, etc.,) and a description of its subject matter; (b) the author or sender of the DOCUMENT; (c) the recipient(s) of the DOCUMENT; (d) the date that the DOCUMENT was authored, sent and received; (e) the circumstances surrounding the removal of the DOCUMENT from YOUR custody, possession or control; and (f) the identity of the person(s) having knowledge of such removal from YOUR custody, possession or control.

As used herein, “KEY OPINION LEADER” or “THOUGHT LEADER” shall mean and refer to physicians, often academic researchers, who are believed by DEFENDANTS to be effective at transmitting messages to their peers and others in the medical community. This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by DEFENDANTS to, amongst other things, consult, give lectures, respond to media inquiries, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or abstracts written by others, sit on advisory boards and make presentations on their behalf at regulatory meetings or hearings.

The phrase “SAMPLES” refers to any medication or unit of a prescription drug not intended to be sold, which is given to promote the drug's sales. This includes any vouchers or coupons that provide for the HEALTHCARE PROVIDERS or patients access to the medication for a specified period of time.

“PATIENT ASSISTANCE PROGRAM” means programs created by drug companies, such as Sanofi, to offer free or low cost drugs to individuals who are unable to pay for their medication. These Programs may also be called indigent drug programs, charitable drug programs or medication assistance programs.

The phrase “SALES REPRESENTATIVE” means any person presently or formerly engaged or employed by YOU whose job duties include calling on physicians or other health care professionals, healthcare facilities, hospitals, and/or physician practice groups; promoting drugs manufactured or licensed by YOU to physicians or other HEALTH CARE PROVIDERS; distributing drug SAMPLES to physicians or other HEALTH CARE PROVIDERS. “SALES REPRESENTATIVE” also includes those who occupy positions titled “Professional Sales Representative,” “Sales Professional,” “Specialty Sales Representative,” “Senior Sales Representative,” “Senior Health Care Representative,” “Professional Representative,” “Health Care Representative”, “Institutional” or “Managed Care” sales representative, “Oncology Sales Representative” “Medical Service Representative”, and “Medical Sales Representative” or any other titles used by Defendants and any of its divisions SALES REPRESENTATIVE also includes any contract employees or SALES REPRESENTATIVES from other companies involved in the promotion or co-promotion of Taxotere (Docetaxel) .

The phrase “SALES MANAGER” means any person presently or formerly engaged or employed by YOU whose job duties include managing SALES REPRESENTATIVES and/or the promotion or marketing of pharmaceutical products in a specific geographic region. “SALES MANAGER” includes those who occupy positions titled “District Sales Manager,” “Senior Regional Sales Manager,” “Regional Sales Manager” and “Area Business Manager”, “Business Manager”, or any other titles YOU use or have used in the past for managers involved in the promotion or marketing of Taxotere (Docetaxel).

The phrase “MEDICAL SCIENCE LIAISON(S)” means any person presently or formerly engaged or employed by YOU for the purpose of sales support and direct field communication with physicians or other HEALTH CARE PROVIDERS about medical and science information related to Taxotere (Docetaxel), and opinion leader management. This includes employees with the titles of “Medical Science Liaison (MSL)”, “Clinical Education Consultant (CEC)” or any other titles YOU use or have used in the past for these employees.

The phrase “MARKETING ORGANIZATION REPRESENTATIVE,” means any person presently or formerly engaged or employed by YOU for the purpose of generating interest in Taxotere (Docetaxel) by creating and implementing a marketing campaign(s) to reach physicians or other HEALTHCARE PROVIDERS. This includes employees with the title of “Marketing Representative” or any other titles YOU use or have used in the past for these employees.

The phrase “CALL NOTES” means any and all writings, notations, electronically stored information, memoranda, DOCUMENTS, emails, database entries and reports or records, internal communications and any other information reflecting any contact with HEALTHCARE PROVIDERS, and/or information about or referring to HEALTHCARE PROVIDERS related to Taxotere (Docetaxel), oncology, treatment of cancer and chemotherapy.

The phrase “TARGETING INFORMATION” means any information the company uses to identify a particular person, group of people, type of health care provider or demographic within a larger audience regarding the promotion of Taxotere (Docetaxel). This includes documentation, including electronically stored information, designating particular campaigns, PROMOTIONAL MATERIAL and/or other promotional efforts directed toward particular types or specialties of healthcare providers (e.g., oncologists) and/or specifically identified healthcare providers.

I. CASE INFORMATION

This DFS pertains to the following case:

Case caption:_____

Civil Action No._____

Court in which action was originally filed:_____

Date this DFS was completed:_____

II. SALE OF TAXOTERE (DOCETAXEL) TO DISPENSER (HOSPITAL/PHARMACY) DIRECTLY AND/OR THROUGH GROUP PURCHASING ORGANIZATIONS

- A. Did YOU sell, distribute, deliver or otherwise provide Taxotere (Docetaxel) to, any HEALTHCARE PROVIDER, either directly or pursuant to a Group Purchasing Organization (“GPO”), identified by the Plaintiff in Sections V. 13 and V.14 of the PFS, during the time period of twenty-four (24) months preceding Plaintiff’s first administration of Taxotere through the Plaintiff’s last administration of Taxotere (Docetaxel)?

Yes_____ No_____

- B. If YOUR answer is “Yes” to Question A. above, please provide a list of all deliveries or shipments of Taxotere (Docetaxel) sold, distributed or otherwise provided to each of the HEALTHCARE PROVIDERS, as identified by the Plaintiff in Sections V. 13 and V.14 of the PFS, for the time period spanning from twenty-four (24) months prior to Plaintiff’s first administration of Taxotere (Docetaxel) through Plaintiff’s last administration of Taxotere (Docetaxel). Please include the name of each HEALTHCARE PROVIDER, the date of shipment/distribution of Taxotere (Docetaxel), and the amount of Taxotere (Docetaxel) distributed on said date.

| Name of Healthcare Provider | Date of Shipment Distribution | Amount of Taxotere Distributed |
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- C. Please provide all DOCUMENTS reflecting sale or purchase agreements regarding Taxotere (Docetaxel) between DEFENDANTS and the HEALTHCARE PROVIDERS identified by Plaintiff in Section Sections V. 13 and V.14 of the PFS in effect during the time period spanning from twenty-four (24) months prior to Plaintiff's first administration of Taxotere (Docetaxel) through Plaintiff's last administration of Taxotere (Docetaxel).
- D. Please provide all DOCUMENTS, including product labels, patient information packets, order forms, purchase orders, billing records, invoices, and other DOCUMENTS related to the shipments of Taxotere (Docetaxel) shipped to the HEALTHCARE PROVIDERS identified by Plaintiff in Sections V. 13 and V.14 of the PFS for the time period spanning from twenty-four (24) months prior to Plaintiff's first administration of Taxotere (Docetaxel) through to Plaintiff's last administration of Taxotere (Docetaxel), and associate each label with the code numbers to which they are applicable. With regard to product labels, identification of the labels that applied to applicable lot numbers or dates is acceptable.

IV. COMMUNICATIONS AND CONTACTS WITH PLAINTIFF'S HEALTHCARE PROVIDERS

- A. For each HEALTHCARE PROVIDER identified in Sections V. 13 and V.14 of the PFS:
1. Identify by name all of Defendants' Sale Representatives, Marketing Organizations Representatives, MEDICAL SCIENCE LIAISONS, and/or any other detail persons ("Representative") who came in contact with any of Plaintiff's HEALTHCARE PROVIDER(S) in connection with Taxotere (Docetaxel) during the timeframe for which such records are available, namely 1996 to present.

| Name of Representative | Title |
|-------------------------------|--------------|
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2. Identify the time period, and specifically the dates, during which the Representative had any such contact with the HEALTHCARE PROVIDER.

| Name of Representative | Healthcare Provider | Dates of Contact |
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3. If the Representative is no longer an employee, Defendants will provide the dates of employment for the employee and will also provide the last known address, telephone number, and email address for the Representative.

| Name of Representative | Dates of Employment | Last Known Address | Telephone Number | Email Address |
|-------------------------------|----------------------------|---------------------------|-------------------------|----------------------|
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4. For each Representative, provide the names of the Representative's Supervising/District SALES MANAGER. If the Representative's Supervising District SALES MANAGER is no longer an employee, Defendants will provide the dates of employment for the employee and will also provide the last known address, telephone number, and email address for the former employee.

| HEALTHCARE PROVIDER | Name of Representative | Date(s) of Contact | Current or Former Employee | Supervising/District SALES MANAGER |
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B. For each Defendants' Sale Representatives, MARKETING ORGANIZATION REPRESENTATIVES, MEDICAL SCIENCE LIAISONS, and/or any other detail persons ("Representative"), previously identified in IV.A of this DFS please produce the following:

1. His/her complete CALL NOTES for each such contact that relates to (a) Taxotere (Docetaxel); and/or (b) hair loss; and/or (c) permanent hair loss and/or alopecia.
2. Produce all emails or other written correspondence with the HEALTHCARE PROVIDER(S) that relates to (a) Taxotere (Docetaxel); and/or (b) hair loss; and/or (c) permanent hair loss and/or alopecia.
3. Produce any and all TARGETING INFORMATION related to the HEALTHCARE PROVIDER(S) identified by Plaintiff in Sections V. 13 and V.14 of the PFS.

C. For the HEALTHCARE PROVIDERS identified by Plaintiff in Sections V. 13 and V.14 of the PFS, please provide the following information related to SAMPLES of Taxotere (Docetaxel):

1. The date(s) on which such SAMPLES of Taxotere (Docetaxel) were provided;
2. The date(s) on which the Taxotere (Docetaxel) was provided through a PATIENT ASSISTANCE PROGRAM;
3. The amount, dosage, and lot numbers of such SAMPLES and/or Taxotere (Docetaxel) provided through a PATIENT ASSISTANCE PROGRAM;
4. The name(s) of the DEFENDANT representative(s) and/or department who provided such SAMPLES Taxotere (Docetaxel);
5. The name(s) of the DEFENDANT representative(s) and/or department who provided Taxotere (Docetaxel) through a PATIENT ASSISTANCE PROGRAM.

| HEALTHCARE PROVIDER | Date(s) Shipped and/or Provided | Amount and Dosage | Lot Number | Representative Who Provided |
|----------------------------|--|--------------------------|-------------------|------------------------------------|
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V. CONSULTING WITH PLAINTIFF’S HEALTHCARE PROVIDER

For each HEALTHCARE PROVIDER identified in Plaintiff’s PFS, please answer the following:

- A. If the HEALTHCARE PROVIDER has been consulted, retained, or compensated by Defendants as a “KEY OPINION LEADER,” “THOUGHT LEADER,” member of a “speaker’s bureau,” “clinical investigator,” “consultant”, advisory board member or in a similar capacity or otherwise has or had a financial relationship with or has been provided REMUNERATION by DEFENDANTS, please state the following for each:
1. Identify the HEALTHCARE PROVIDER.
 2. Identify the date(s) that the HEALTHCARE PROVIDER was consulted, retained, or compensated.

3. State the nature of the affiliation.
4. State the type amount of REMUNERATION provided to the HEALTHCARE PROVIDER.

| HEALTHCARE PROVIDER | Date(s) Consulted, Retained, or Compensated | Nature of Affiliation | REMUNERATION |
|---------------------|---|-----------------------|--------------|
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5. Please identify and produce any and all consulting agreements/contracts and/or retainer agreements/contracts entered into by DEFENDANTS with the HEALTHCARE PROVIDERS identified in Sections V. 13 and V.14 of the PFS.

VI. PLAINTIFF'S HEALTHCARE PROVIDER'S PRACTICES

- A. Provide all chemotherapy related prescriber-level data designed to track prescribing or treating practices that YOU obtained on Plaintiff's HEALTHCARE PROVIDERS identified in Sections V. 13 and V.14 of the PFS.
- B. Was the HEALTHCARE PROVIDER(S) identified in Sections V. 13 and V.14 of the PFS involved in any clinical trial sponsored by DEFENDANTS related to the treatment of cancer?

_____ Yes _____ No

If yes, provide the final Investigator Protocol related to any such trial(s).

- A. Did the Plaintiff's HEALTHCARE PROVIDER ever report any adverse events to DEFENDANTS as they pertain to Taxotere (Docetaxel)?

_____ Yes _____ No

If yes, provide all DOCUMENTS related to the adverse event report/MedWatch form.

CERTIFICATION

I am employed by _____, one of the DEFENDANTS in this litigation. I am authorized by _____ [name of other DEFENDANTS] to execute this certification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individual, including counsel for

DEFENDANTS, upon whose advice and information I relied. I declare under penalty of perjury subject to 28 U.S.C. § 1746 that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge and that I have supplied all requested DOCUMENTS to the extent that such DOCUMENTS are in my possession, custody and control (including the custody and control of my lawyers).

Signature

Print Name

Date